76. (New) An immunogenic composition according to Claim 74 further comprising at least one additional immunologic component covalently attached to said peptidyl core matrix.

77. (New) An immunogenic composition according to Claim 76 wherein the additional immunologic component is an immunogenic portion of a pathogen selected from the group consisting of diphtheria, pertussis, tetanus, measles and polio virus.

78. (New) An immunogenic composition according to Claim 74 wherein the peptidyl core matrix comprises at least one lysine.

79. (New) An immunogenic composition according to Claim 71 wherein the immune response is to glucosyltransferase and results in the reduction of the colonization or accumulation of *S. sobrinus* streptococcal strains in a mammal to whom the vaccine composition is administered.

80. (New) An immunogenic composition according to Claim 74 wherein the immune response is to glucosyltransferase and results in the reduction of the colonization or accumulation of *S. sobrinus* streptococcal strains in a mammal to whom the vaccine composition is administered.

REMARKS

Interview

Applicants appreciate that the Examiner participated in an interview with Lisa M. Treannie, Esq., on November 16, 2001 to discuss the pending claims and rejections.

Claim Amendments

Claims 1-11 and 15-19 have been cancelled. Non-elected Claims 18-19 are cancelled without prejudice to their reinstatement in this or a continuing application. Non-elected claims

12 and 14 have been amended to facilitate consideration of rejoinder upon allowance of the elected claims.

New Claims 20-80 have been added. The newly added claims more particularly point out and distinctly claim Applicants' invention. Specifically, a claim set has been added to correspond to each of the 6 different glucosyltransferases (*S. mutans* glucosyltransferase-B, *S. mutans* glucosyltransferase-C, *S. mutans* glucosyltransferase-D, *S. downei* glucosyltransferase-S, *S. downei* glucosyltransferase-I and *S. sobrinus* glucosyltransferase-2) presented in Substitute Table 1 on page 21. Each glucosyltransferase claim set further recites specific amino acids or amino acid sequence subunits of each organisms' indicated glucosyltransferase. Support for these amendments may be found throughout the Specification, particularly page 3, line 3, through page 5, line 2, and Table 1 on page 21. Additionally, Applicants have amended the claims to recite immunogenic compositions; immunogenic compositions may or may not confer protection against challenge with the immunizing agent. Support for this amendment may be found in the Specification on page 7, line 23 to page 8, line 2. No new matter has been added.

Rejection of Claims 1, 4-5, 7-11, 15 and 17 Under 35 U.S.C. §112, Second Paragraph

Claims 1, 4-5, 7-11, 15 and 17 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Although Claims 1-11 and 15-17 have been cancelled, Applicants will address the rejection in view of the newly added claims. The Examiner states that the claims are indefinite because there is no defined specific amino acid sequence in the claims.

The newly added claims recite specific amino acids and amino acid sequence subunits of glucosyltransferases for each of the recited glucosyltransferases. As such, the newly added claims are even more clear and definite. In view of the claim amendments, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-4 and 15-17 Under 35 U.S.C. §102(b)

Claims 1-4 and 15-17 are rejected under 35 U.S.C. §102(b) as being anticipated by Shiroza *et al.* (*J. Bacteriol. 169*:4263-4270 (1987)). The Examiner states that Shiroza *et al.* teach

a polypeptide sequence which is 100% identical to the polypeptide sequence of SEQ ID NO:1 and SEQ ID NO: 3 of the instant application. The Examiner further states that the features upon which Applicants rely (*i.e.*, useful peptides will be less than the complete amino acid sequence of the intact GTF enzyme) are not recited. Applicants respectfully traverse this rejection.

As previously stated, Shiroza *et al.* teach the entire sequence of the *S. mutans* GTF-B gene and corresponding protein. In order to expedite prosecution the newly added claims recite that the amino acid sequence is a subunit of the glucosyltransferase protein. See the Specification page 3, lines 3-7. Applicants further state that "peptides will be of sufficient length to raise an immune response in a mammal to whom it is administered but will be less than the complete amino acid sequence of the intact GTF enzyme. Typically, the peptide will be at least 5-7 amino acids in length. Preferably the peptide will be at least 12 amino acids in length; more preferably the peptide will be at least 19, 20 or 21 amino acids in length." Support can be found on page 9, lines 9-13. Shiroza *et al.* does not provide any teaching or suggestion of peptides which are less than the full length of the GTF-B protein. The Shiroza reference does not teach or suggest an immunogenic composition of any type. Moreover, Shiroza *et al.* does provide any teaching or suggestion even with regard to the entire sequence of a glycosyltransferase other than *S. mutans* glucosyltransferase-B. Shiroza *et al.* merely discuss the existence of other glucosyltransferases. Applicants' newly added claims recite an immunogenic composition comprising a subunit of a particular glucosyltransferase, and Applicants also provide specific amino acid sequences. Shiroza *et al.* does not provide any teaching or suggestion which would lead the ordinarily skilled artisan to select the particular amino acids or amino acid sequence subunits recited in the claims to produce the claimed immunogenic compositions. Thus, Shiroza *et al.* does not anticipate the invention as claimed. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-11 and 15-17 Under 35 U.S.C. §103(a)

Claims 1-11 and 15-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shiroza *et al.* and Taubman *et al.* (U.S. Patent No. 5,686,075). The Examiner states that Shiroza *et al.* has identical protein activity and identical immunogenicity to the claimed polypeptide.

As stated above and previously, Applicants reiterate that Shiroza *et al.* do not teach or suggest the claimed specific glucosyltransferase peptide subunit portions, which are less than the full length protein. Further, Shiroza *et al.* do not teach or suggest immunogenic compositions of any kind. Taubman *et al.* do not remedy these defects, as Taubman *et al.* do not teach or suggest the specific peptide subunits of the glucosyltransferase of the instant claims. Applicants have further defined these peptides in the specification as being less than the whole protein. Shiroza *et al.* does not provide any teaching or suggestion which would lead the ordinarily skilled artisan to select the particular amino acids or amino acid sequence subunits recited in the claims to produce the claimed immunogenic compositions. Additionally, the peptides disclosed by Taubman *et al.* are not identical to Applicants' peptide immunogenic compositions, because the specified amino acids and amino acid sequences of the indicated glucosyltransferases are structurally different. Thus, the claims are not obvious in view of the teachings of the cited references alone or in combination. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Pamela A. Torpey

Pamela A. Torpey
Registration No.: 45,736
Telephone (978) 341-0036
Facsimile (978) 341-0136

Concord, MA 01742-9133
Dated: December 18, 2001

MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

12. (Amended) A method of provoking an immune response to glucosyltransferase in mammals comprising administering a peptide consisting essentially of an amino acid sequence subunit of *S. mutans* [of] glucosyltransferase-B comprising an amino acid selected from the group consisting of aspartate 562, aspartate 567, histidine 561, tryptophan 491, glutamate 489, [an equivalent of aspartate 562, an equivalent of aspartate 567, an equivalent of histidine 561, an equivalent of tryptophan 491, an equivalent of glutamate 489,] and combinations thereof, and which is of sufficient length to raise an immune response in the mammal, to the mammal, which thereby provokes said immune response.

14. (Amended) A method of immunizing a mammal against dental caries comprising administering a peptide consisting essentially of an amino acid sequence subunit of *S. mutans* [of] glucosyltransferase-B comprising an amino acid selected from the group consisting of aspartate 562, aspartate 567, histidine 561, tryptophan 491, glutamate 489, [an equivalent of aspartate 562, an equivalent of aspartate 567, an equivalent of histidine 561, an equivalent of tryptophan 491, an equivalent of glutamate 489,] and combinations thereof, and which is of sufficient length to raise an immune response in the mammal, to the mammal.